IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.

10/049,427

Confirmation No. 1087

Applicant

Thor

Filed

6 May 2002

TC/A.U.

1617

Examiner

Yong Soo Chong

Docket No. :

4220-78-PUS

Customer No.:

22442

Declaration of David A. Rivas, MD 37 CFR 1.132

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

Dear Sir:

I, David A. Rivas, declare as follows:

My curriculum vitae is attached. My employment and educational history is summarized below.

<u>Johnson & Johnson Pharmaceutical Research and Development</u>, Senior Director, Clinical Leader [Reproductive Health/Urology] August 2004-present

GlaxoSmithKline, Director, Discovery Medicine [Urogenital], Cardiovascular & Urogenital Center for Excellence and Drug Discovery November 2003-August 2004

Pfizer, Inc., Director, Global Clinical Research [Urology] April 2003-October 2003

<u>Pharmacia Corporation</u>, Director, Global Clinical Research [Urology] Associate Director, Global Clinical Research [Urology] Nov. 2000-Dec. 2002

Various Faculty Appointments, 1994-2000

Various Post Graduate Positions, 1984-1994

M.D., Jefferson Medical College of Thomas Jefferson University Philadelphia, Pennsylvania, 1980-1984

A.B., Distinction in All Subjects, Cornell University Ithaca, New York, 1977-1980

- I have reviewed U.S. Patent Application 10/049,427, the Office Action dated 10/4/2005 and the references cited therein, including the McMahon et al. article cited by the Examiner in the 10/4/05 Office action (McMahon et al., J Urology, v. 161, pp. 1826-30 (1999). Treatment of Premature Ejaculation with Paroxetine Hydrochloride as Needed: 2 Single-Blind Placebo Controlled Crossover Studies).
- 2. McMahon et al. is a pilot study exploring the merits of paroxetine (an SSRI specifically designed to treat conditions pertaining to mood and affect and which must be administered daily to achieve and maintain the desired therapeutic effect) in the treatment of men suffering with premature ejaculation (PE). The authors study objective is 'to determine whether paroxetine as needed 3-4 hours before sexual intercourse was more efficacious than placebo in the treatment of PE.'
- 3. McMahon et al. does not provide sufficient information to determine whether the week 1 treatment data of Study 1 are statistically significantly different from the control data. Since McMahon et al. does not state that the week 1 treatment data of Study 1 are statistically significantly different from the control data, I would assume that they are not. Consequently, I would not rely on the week 1 data as demonstrating an increase in ejaculatory latency.
 - a. In relation to Study 1, the authors state that "[t]he ejaculatory latency time for groups A and B during treatment with paroxetine as needed was statistically superior to placebo at 2, 3, and 4 weeks (p<0.001, table 2, fig. 1)." This statement conveys to me, as one skilled in the art, that the authors do not consider the results at week 1, shown in table 2 and figure 1, to be statistically significant. Based on the authors' characterization of this data, it would be inappropriate for one to conclude that the week 1 data in Study 1 are statistically significant.
 - to permit interpretation of the week 1 data, particularly because of the

- limited sample size and because intravaginal ejaculatory latency times (IELT) tend to be variable and not normally distributed.
- c. As one skilled in the art, after reviewing the McMahon et al. paper and understanding that the week 1 data in Study 1 are not statistically significant, it would be inappropriate for one to conclude that the week 1 data demonstrates a statistically significant increase over control data in ejaculatory latency time. Therefore, I would not rely on the week 1 data as demonstrating an increase in ejaculatory latency.
- 4. McMahon et al.'s conclusions regarding as needed dosing of paroxetine does not allow one skilled in the art to draw any conclusions about whether or not as needed use of paroxetine in the absence of priming doses is efficacious because the "as needed" use of paroxetine in McMahon et al. does not preclude priming doses.
 - a. As noted above, the study objective of McMahon et al. was 'to determine whether paroxetine as needed 3-4 hours before sexual intercourse was more efficacious than placebo in the treatment of premature ejaculation.'
 - b. McMahon et al.'s statement that initial daily treatment improves the as needed efficacy of paroxetine was based on a greater mean ejaculatory latency time in Study 2 (initial daily dosing) than in Study 1 (no initial daily dosing). (McMahon et al., p. 1829, col. 1, ll. 20-25);
 - c. Mean ejaculatory latency time for study Groups A-D is calculated using all data throughout the treatment phases (i.e., multiple instances of intercourse per week over 4 week treatment phases) when paroxetine had been used over a period of time;
 - d. Paroxetine use throughout a 4 week period, even in Study 1 without prior 2 week daily dosing, is not "in the absence of a priming dose";
 - e. The McMahon et al. study design did not impose a minimum time interval between intercourse episodes and therefore, paroxetine from one dose that was not cleared from the body could, in combination with a subsequent dose, result in an increase in paroxetine exposure in the patient greater than a single dose, thereby functioning as a priming dose;

- f. Therefore, McMahon et al.'s statement that "paroxetine as needed is significantly better if patients are initially treated with the drug daily," which is based on mean ejaculatory latency time, is not relevant to whether paroxetine is effective in the absence of a priming dose because the "as needed" use of paroxetine in McMahon et al. was not designed to avoid a priming dose effect.
- 5. The present application on p. 19, ll. 20-25 describes as needed dosing in the absence of priming doses. The concept of a priming dose refers to a prior dose of a drug that has not been cleared from the body at the time of administration of a subsequent dose of the drug.
- 6. There are a number of scientific and methodological issues in McMahon et al. that makes one question the results and therefore, makes it difficult to draw meaningful conclusions from the study regarding the study objective or whether paroxetine can be therapeutically effective as needed in the absence of priming doses, a question that was not even contemplated by the study.
 - a. <u>Primary/Secondary Premature Ejaculation</u>. The patient characteristics in McMahon et al. (Table 1) indicate that the study included men with both primary and secondary PE. The paper, however, does not specify how the patients with primary and secondary PE were distributed between Groups A and B. It is unclear, therefore, whether an uneven distribution of primary or secondary PE patients between the Groups may have introduced some bias in the study.
 - b. Absence of Adverse Events. McMahon et al. state that there were no side effects reported by the patients taking paroxetine as needed in Study 1 (i.e., no headache, dizziness, somnolence, anorexia, anejaculation, gastrointestinal upset, reduced libido, erectile dysfunction, etc.). This would be unusual for any study and especially unusual for a study with a compound (paroxetine) with known side effects. This result draws into question the integrity of the data collection methods. Therefore, it is difficult to draw meaningful conclusions from the study.

- c. <u>Behavior Modification/Bias</u>. There are two examples of potential bias in the McMahon et al. study: clinical investigator (physician) bias due to a lack of blinding of the investigator and patient bias based on stopwatch usage.
 - i. <u>Blinding</u>. Patients with PE can respond to factors other than pharmaceutical treatment, such as suggestions, even inadvertent, from a physician. The McMahon studies were single-blind studies (the patient is blinded to whether he is taking placebo or drug, but the clinician is not). Therefore, the physicians could have provided inadvertent suggestions to patients that they would or would not see an effect based on whether paroxetine or placebo was being administered, thereby influencing the reported results to show a stronger treatment effect. The McMahon et al. study, being a single blind, rather than a double blind study, calls the results of the study into question, making it difficult to make meaningful conclusions.
 - ii. Stopwatch Measurement. McMahon et al. did not report the directions for stopwatch measurement of ejaculatory latency time. The manner in which this time interval is measured (e.g., whether the stopwatch is held by the patient or his partner) can introduce bias into reported results, particularly in a single blind study. This factor also raises questions about the reported results making meaningful conclusions based on the study difficult to draw.
- d. <u>Pretreatment Values</u>. McMahon et al. report pretreatment values of IELT based on a three week baseline period whereas the pretreatment values of coitus frequency were based on a three month pretreatment period, and the study measures of IELT and coitus frequency are based on one week values. These differences in measurements make meaningful conclusions based on the results difficult.
- 7. I hereby declare that all statements made herein of my own are true and that all statements made on information and belief are believed to be true; and

further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the subject application or any patent issuing therefrom.

Date David A. Rivas, MD

CURRICULUM VITAE

David A. Rivas, MD

Home Phone: 215-297-5516 Mobile: 215-688-2007 Home Fax: 215-297-5478

Email:

davidrivas@comcast.net

Pharmaceutical Industry Experience

Senior Director, Clinical Leader [Reproductive Health/Urology] August 2004-present Johnson & Johnson Pharmaceutical Research and Deveopment 920 Route 202 Raritan, NJ 08869

Responsibilities

Clinical Development Program Team Leader

- Develop Ph II clinical trials of a compound in the treatment of overactive bladder
- Regulatory submissions/interactions regarding the lead compound
- Submission of electronic IND May 2005
- Development of Clinical Development Plan
- Management of study and clinical activity budgets
- Develop clinical program for alternate indications for the compound
- Development of clinical trial protocols
- Establish and manage budget of clinical trials
- Contribute to Compound Development Team, including clinical report
- Review of candidate compounds for In-Licensing/Due Diligence
- Develop Global Advisory Board and board meetings
- Consultant to early development efforts to develop candidate compounds

Project physician, dapoxetine

- Develop Ph I and III clinical trials of dapoxetine in the treatment of premature ejaculation
- Interactions with regulatory agencies
- Submission of electronic NDA Dec 2004
- Assist with development of Clinical Development Plan
- Management of clinical study budgets
- Develop clinical program for line extension indications for the dapoxetine
- Development of clinical trial protocols
- Initiate and manage clinical trials, including budget
- Monitor and conduct clinical trials
- Contribute to Clinical Development Team
- Participate with KOLs on dapoxetine advisory boards

Director, Discovery Medicine [Urogenital] November 2003-August 2004
Cardiovascular & Urogenital Center for Excellence and Drug Discovery
GlaxoSmithKline
709 Swedeland Road
King of Prussia, Pennsylvania 19406
Responsibilities

Clinical Matrix Team Leader

- Develop Ph II clinical trials of 4 compound for the treatment of overactive bladder and premature labor
- Regulatory submissions/interactions regarding the compounds
- Submission of IND June 2005
- Development of Clinical Development Plan
- Management of study and clinical activity budgets
- Develop clinical programs for the compounds
- Development of clinical trial protocols
- Establish and manage budget of clinical trials
- Contribute to Project Team, including clinical report
- Review of candidate compounds for In-Licensing/Due Diligence
- Develop Global Advisory Board and board meetings
- Consultant to preclinical development efforts to develop candidate compounds
- Develop strategy for urogenital discovery medicine

Director, Global Clinical Research [Urology] April 2003-October 2003 Pfizer, Inc., 100 Route 206 North, Peapack, New Jersey 07977 Director, Global Clinical Research [Urology] Jan 2003-April 2003 Associate Director, Global Clinical Research [Urology] Nov 2000-Dec 2002 Pharmacia Corporation, 100 Route 206 North, Peapack, New Jersey 07977 Responsibilities

Tolterodine Clinical Development Program Team Leader

Initiate, conduct, and report Phase I/II and III clinical trials of tolterodine for voiding dysfunction and incontinence, interactions with regulatory agencies regarding the investigation, registration, and safety of tolterodine

- Development and annual revision of Clinical Development Plan
- Management of budget for all clinical activities
- Develop clinical programs
- Development of clinical trial protocols
- Establish and manage budget of clinical trials
- Monitor and conduct clinical trials
- Compose final clinical trial study reports
- Contribute to Brand Development Team
- Clinical report to Project Development Team
- Review of candidate compounds for In-Licensing Lead Generation Team
- Participate with KOLs on Tolterodine Global and US advisory Boards
- Contribute to regulatory submissions
- Correspondance/Response to regulatory agency inquiries
- Preparation of annual regulatory clinical safety reports

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Regulatory submissions
Tolterodine PR Mutual Recognition Procedure – Approval July 11, 2001

Japan NDA submission 26 February 2002

Pediatric sNDA submission 14 October 2003, 6 months exclusivity granted April 2004

Instructional Courses: Drug Development	
CRO-Investigator Support Initiative	11/29-12/1/00
PERI Global Clinical Trials	2/21-3/01
PERI Drug Development I	2/5-7/01
PERI Drug Development II	6/11-13/01
DIA Statistics	3/26-7/01
EAGLE Initiative I	3/29-31/01
Franklin-Covey Leadership	5/14-15/01
Decker Speaker Training	5/16/01
Medical Writing I	7/25-6/01
Franklin-Covey WMM	7/23/01
EAGLE Initiative II	8/30-1/01
Success with CROs Training Course	9/24-5/01
Barnett Pediatric Clinical Trials	12/5-7/01
DIA Contemporary Pharmacovigilance and Risk Management	1/14-17/02
DIA Regulatory II: Marketing Application and Post-Approval Phase	2/18-20/02
DIA Japan: Pharmaceutical Development, Registration, and Culture	2/24-5/02
PERI NDA Game: FDA/Industry Interaction in Drug Development	4/3-5/02
Frontline Manager Training	5/9-10/02
Project Leadership Training	8/12-13/02
PERI FDA/Industry Project Management	9/9-11/02
Managing Business Risk	10/23/02
DIA European Regulatory Affairs	11/11/02
Developing a Resilient Organization	12/10/02
DIA Navigating HIPAA Regulations	4/11/03
DIA Pharmacokinetic and Pharmacodynamic Application	
in the Drug Development Process	4/3-5/2004
PERI Basic Pharmacology Training Course	4/19-21/2004
AAPS/FDA Workshop on Pharmacokinetics and Pharmacodynamics	
of Drugs in Pregnancy and Lactation	5/3-4/2004
GSK Drug Development Simulation Training	7/27-30/2004
J&J Manager and the Law	9/9-10/2004
J&J On the Starting Blocks Clinical Trial Conduct	10/12-5/2005
J&J MedDRA training	12/16/2004
J&J Presentation Skills	6/8/2005
DIA IND and CTA/NDA Regulatory Affairs Training	8/1-4/2005

CV David Rivas MD 3(37) Education

M.D., Jefferson Medical College of Thomas Jefferson University Philadelphia, Pennsylvania 1980-1984

A.B., Distinction in All Subjects, Cornell University Ithaca, New York 1977-1980

Post Graduate

Fellowship: Neuro-Urology and Incontinence Thomas Jefferson University Hospital Philadelphia, Pennsylvania 1992-1994

Residency: Urology Thomas Jefferson University Hospital Philadelphia, Pennsylvania 1987-1991

Assistant Surgeon: Chestnut Hill Hospital Philadelphia, Pennsylvania 1986-1987

Residency: Surgery Cooper Hospital/University Medical Center Camden, New Jersey 1985-1986

Internship: Surgery Medical College of Pennsylvania Philadelphia, Pennsylvania 1984-1985

Specialty Review in Urology: Cook County Graduate School of Medicine Chicago, Illinois 1991

Faculty Appointments

Assistant Professor of Urology
Department of Urology
Jefferson Medical College of Thomas Jefferson University
Philadelphia, Pennsylvania
1994-2000

Director, Division of Neuro-Urology Department of Urology Jefferson Medical College of Thomas Jefferson University Philadelphia, Pennsylvania 1996-2000

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Director, Urology Residency Program
Department of Urology
Jefferson Medical College of Thomas Jefferson University
Philadelphia, Pennsylvania
1995-2000

Director, Transurethral Microwave Thermotherapy Treatment Center Department of Urology Jefferson Medical College of Thomas Jefferson University Philadelphia, Pennsylvania 1997-2000

Instructor of Urology Department of Urology Jefferson Medical College of Thomas Jefferson University Philadelphia, Pennsylvania 1992-1994

Faculty, Incontinence Center Thomas Jefferson University Philadelphia, Pennsylvania 1992-2000

Attending Physician Thomas Jefferson University Hospital Philadelphia, Pennsylvania 1992-2000

Consulting Physician Magee Rehabilitation Hospital Philadelphia, Pennsylvania 1993-2000

Consulting Physician Wills Eye Hospital Philadelphia, Pennsylvania 1995-2000

Urology Practice

Tri-County Urologic Associates, PC Pottstown, Pennsylvania 1991-1992

Medical Licensures

New Jersey #MA46969 issued 1985 Pennsylvania #MD034854E issued 1985 Oregon #19179 (inactive) issued 1995 Delaware #C10005641 issued 1999 Drug Enforcement Administration #BR0232506

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Certifications

Recertification, American Board of Urology February 28, 2002

Instructor for Physician Certification Transurethral Microwave Thermotherapy of the Prostate EDAP/Technomed Norcross, GA 1997

Fellow, American College of Surgeons October 26, 1995

Advanced Laser Training Program in The VersaPulse Select Urology Laser Temple University Hospital Philadelphia, Pennsylvania November 11, 1994

Certification, American Board of Urology February 28, 1993

Operative Laparoscopy for the Urologist Including Contact Nd:YAG Laser Therapy Thomas Jefferson University Hospital Philadelphia, Pennsylvania, 1991

Extracorporeal Shock Wave Lithotripsy The Mid-Atlantic Kidney Stone Center Marlton, New Jersey, 1989

Laser Education Program Thomas Jefferson University Philadelphia, Pennsylvania, 1989

National Board of Medical Examiners Philadelphia, Pennsylvania Diplomate #291267, granted 1985

CV David Rivas MD 6(37)

Professional Societies

American Medical Association
Pennsylvania Medical Society
Montgomery County Medical Society
American Urological Association
Urological Association of Pennsylvania
International Continence Society
Society for Urodynamics and Female Urology
American College of Surgeons
Societe Internationale D'Urologie

Educational programs

Program Director
"Practical Urology for the Primary Care Physician"
Thomas Jefferson University, Philadelphia PA
November 11, 1993

Program Director

"Transurethral Microwave Thermotherapy of the Prostate Using the Prostatron" Physician Training and Certification Courses Thomas Jefferson University, Philadelphia PA 8/18/97, 9/22/97, 12/15/97, 2/9/98, 6/15/98

Invited Speaker

"Transurethral Microwave Thermotherapy: Prostasoft 2.0 and 2.5" "Perioperative Challenges of the New Millenium" Continuing Medical Education Course Thomas Jefferson University, Philadelphia, PA 5/14/98

Program Director

"Transurethral Microwave Thermotherapy: Prostasoft 2.0 and 2.5" Continuing Medical Education/Physician Certification Course Stanford University, Stanford CA 7/16/99

Invited Speaker

"Sacral Nerve Root Stimulation for the Treatment of Urgency Incontinence" Continuing Medical Education Course Thomas Jefferson University, Philadelphia, PA 7/15/99

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Committees and Academic Services

Committee on Alumni and Public Affairs, Thomas Jefferson University, 1994-2000 Monthly medical student lectures, Jefferson Medical College, 1994-2000 Dean's Committee on Medical Ethics Education, 1996.

Committee on Graduate Medical Education, 1996-2000.

Judge-Resident Essay Prize Competition, Mid-Atlantic Section of the American Urological Association Annual Meeting, Hot Springs, VA, September 1997 Scientific Session Moderator, Mid-Atlantic Section of the American Urological Association Annual Meeting, Hot Springs, VA, September 1997 Committee on Continuing Medical Education 2000-present

National Courses/Conferences

Invited Speaker
"Skeletal muscle-assisted micturition and continence,"
Urology Instructional Course, "State of the Art in Neuro-Urology,
Neurostimulation and Neuromodulation"
American Spinal Injury Association 22 nd Annual Meeting
Seattle, WA, April 23, 1996.

Faculty: "Urodynamics"
American Urological Association Postgraduate Course
American Urological Association Surgical Learning Center
Houston, TX, October 12-13, 1996

Faculty: American Urological Association Office of Education
"Bladder dysfunction in neurologic disease: diagnosis and management"
American Urological Association National Convention San Diego CA, June 1998

Faculty: "Advances in Drug Therapies and Drug Delivery Systems" International Continence Society Instructional Course International Continence Society Annual Convention Denver, CO, August 23, 1999

Editorial Article Reviewer

Neurourology and Urodynamics Journal of Urology American Journal of Physiology

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Grants

"Functional, histological, and Molecular Analysis of Vanilloid Effect on Lower Urinary Tract Dysfunction"

Nemours Foundation

Principal Investigator, 2000

"A Randomized, Parallel-Group, Double-Blind, Placebo-Controlled Study Comparing the Safety, Tolerance, and Efficacy of RTX (resiniferatoxin) Topical Solution in Patients with Detrusor Hyperreflexia"

Afferon Corporation

Principal Investigator, 2000

"A Phase III, Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of the Efficacy and safety of Controlled-Release Darifenacin Versus Tolterodine in the Treatment of Subjects with Overactive Bladder" Pfizer, Inc

Principal Investigator, 2000

"Dose-response Study of SB 223412 Effect on Bladder Function in the Rat Model of Spinal Cord Injury" SmithKline Beecham Pharmaceuticals Principal Investigator, 2000

"Prospective Evaluation of the Urethral Drainage Stent (UDS) for Patients with Urinary Retention Secondary to Prostate Obstruction"
Microvasive, Boston Scientific Corporation
Co-investigator 1999 - 2000

"Sacral Nerve Stimulation for Chronic Voiding Dysfunction" Medtronic Grant MDT-103 Medtronic Neurological Principal Investigator, 1998-9

"Post-approval Sacral Nerve Stimulation Study for the Treatment of Urinary Voiding Dysfunction" Medtronic Grant MDT-103
Medtronic Neurological
Principal Investigator, 1999-2000

"In-Vivo Whole-bladder Response to SB223412 and Capsaicin in the Rat Model of Spinal Cord Injury"
SmithKline Beecham Pharmaceuticals
Principal Investigator, 1998-9

"An Open-label Study to Evaluate Patient Acceptance and Safety of OROS Oxybutynin Chloride in Urge Urinary Incontinence"
Alza Corporation
Principal Investigator, 1998-9

"A Dose Escalating, Single-Blind, Placebo-Controlled Trial Evaluating the Safety, Tolerance, and Effects of Resiniferatoxin" Afferon Corporation Principal Investigator, 1997-1999

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"Dose Escalation Study of Tolterodine in Patients with Urinary Incontinence" Pharmacia & Upjohn Principal Investigator, 1997-8

"Molecular Analysis of Neurogenic Lower Urinary Tract Dysfunction" Nemours Foundation Principal Investigator, 1997-2000

"Intravesical Capsaicin for Treatment of Hyperreflexic Bladder" American Paraplegia Society Co-Investigator, 1995-1996

"Molecular Analysis of Normal Bladder and Interstitial Cystitis" Thomas Jefferson University Dean's Overage Research Program Co-Investigator, 1995-1996

"Bladder Physiology and Functional Recovery after Experimental Spinal Cord Injury" American Foundation for Urologic Disease Principal Investigator, 1993-1995

"Comparison of Sphincter Prosthesis and Sphincterotomy" National Center of Medical Rehabilitation Research at the National Institute of Child Health and Human Development Co-Investigator, 1993-1996

"Multicenter Open Label Study of the Safety and Efficacy of Oral Lomefloxacin as a Prophylactic Agent in Transrectal Prostate Biopsy" Searle Pharmaceuticals Co-Investigator, 1992-1994

"Prospective Evaluation of Terazosin in Spinal Cord Injured Men" Abbott Pharmaceutical Co-Investigator, 1992-1994

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Honors and Awards

- 1. 26th Annual Meeting of the American Spinal Injury Association 2000 Accorda Therapeutics 1st prize winner "Intravesical resiniferatoxin (RTX) treatment of detrusor hyperreflexia: results of a randomized single-blind, placebocontrolled multicenter trial"
- 2. 2000 Philadelphia Urological Society 2nd place Basic Science Category Resident Essay "Methylprednisolone and mianserin improve recovery of bladder function after spinal cord injury in the rat model"
- 3. 1999 Philadelphia Urological Society 1st place Basic Science Category Resident Essay "Molecular analysis of bladder smooth muscle actin isomers in a rat model of spinal cord injury."
- 24th Annual Meeting of the American Spinal Injury Association 1998 Accorda Therapeutics 1st prize winner "Bladder smooth muscle isoactin gene expression in the rat model of spinal cord injury"
- 1997-8 AUA/Circon ACMI Prize Essay Contest, Co-author Third Place, Clinical Research Category "Sphincter stent versus external sphincterotomy in spinal cord injured men; prospective randomized multicenter trial"
- 6. 23rd Annual Meeting of the American Spinal Injury Association 1997 Poster Competition, First Place Award "Electrically stimulated skeletal muscle urinary neosphincter for stress urinary incontinence"
- 22 nd Annual Meeting of the American Spinal Injury Association
 1996 Poster Competition Second Place Award
 "Gracilis urethromyoplasty-the creation of a new autologous urinary sphincter in neurologically impaired patients"
- 1995 Mid-Atlantic Section of the American Urological Association Basic Science Essay-2nd place prize "Gracilis muscle dynamic urethral sphincter myoplasty: rat model experience"
- 1995 Philadelphia Urological Association
 Annual Resident Essay Contest, First Prize, Clinical Research
 "Management of sphincter dyssynergia in SCI men with indwelling catheter using the sphincter stent prosthesis"
- 10. 21rd Annual Meeting of the American Spinal Injury Association1995 Poster Competition, First Place Award"Gracilis muscle dynamic urethral sphincter myoplaty: rat model experience"
- 11. 1994 Philadelphia Urological Association Annual Resident Essay Contest Third Prize, Clinical Research "Latex allergy in spinal cord injury"

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- 12. 20th Annual Meeting of the American Spinal Injury Association1994 Poster Competition, First Place Award"Three year follow-up of the urinary sphincter stent for the treatment of sphincter dyssynergia in spinal cord injury patients"
- 13. 20th Annual Meeting of the American Spinal Injury Association 1994 Poster Competition, First Place Award "Complications of vacuum constriction device for treatment of erectile dysfunction in spinal cord injury men"
- 14. 20 th Annual Meeting of the American Spinal Injury Association 1994 Poster Competition Second Place Award "Detrusormyoplasty: skeletal muscle wrap of the urinary bladder; animal and clinical experience"
- 15. 1993 American Urological Association
 Jack Lapides Essay Contest on Neuro-Urology/Urodynamics, Grand Prize,
 Co-Author "Evaluation of skeletal muscle wrap of the urinary bladder and functional
 neuromuscular electrical stimulation: detrusor myoplasty"
- 16. 1993 Philadelphia Urological Association Annual Resident Essay Contest, Second Prize, Basic Research "Micturition patterns in rat model spinal cord injury"
- 17. 1993 World Congress on Endourology
 Essay Contest, 1st Prize
 "Prospective evaluation of external sphincter prosthesis placement with external sphincterotomy in spinal cord injured men"
- 18. 1993-95 American Foundation for Urologic Disease Research Scholar "Bladder physiology and functional recovery following experimental spinal cord trauma"

Electronic Education

- 1. Chancellor, M.B., Rivas, D.A.: Urinary Incontinence. Williams & Wilkins' World Wide Web Medical School Education. 1996.
- 2. Rivas, D.A., Chancellor, M.B.: Benign Prostatic Hyperplasia. Williams & Wilkins' World Wide Web Medical School Education. 1996.

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Publications

- 1. Bagley, DH and Rivas, DA: Upper urinary tract filling defects: flexible ureteroscopic diagnosis. J Urol 143: 1196, 1990.
- 2. Chancellor, MB, Rivas, DA, Erhard, MJ, Hirsch, IH, Bagley, DH: Flexible cystoscopy during urodynamics of spinal cord injured patients. J Endourology, 7(6); 531-535, 1993.
- 3. Rivas, DA, Chancellor, MB, Hill, K, Friedman, M: Neurologic manifestations of baclofen withdrawal. J Urol 150: 1903-1905, 1993.
- 4. Chancellor, MB and Rivas, DA: The American Urological Association symptom index for women with voiding symptoms; lack of specificity for benign prostatic hyperplasia. J Urol 150: 1706-1709, 1993.
- 5. Chancellor MB, Erhard MJ, Rivas DA: Clinical effect of alpha-1 antagonist terazosin on external and internal urinary sphincter.

 J American Paraplegia Society, 16:207-214, 1993.
- 6. Abdill, CK, Rivas, DA, Chancellor, MB: Transurethral placement of external sphincter wire mesh stent for neurogenic bladder.

 American Association Spinal Cord Injury Nurses 11(2):38-41, 1994.
- 7. Chancellor, MB, Rivas, DA, Huang, B, Kelly, G, Salzman, SK: Micturition patterns after spinal trauma as a measure of autonomic functional recovery. J Urol 151: 250-254, 1994.
- 8. Chancellor, MB, Erhard, MJ, Kiilholma, PJ, Rivas, DA: Functional urethral closure with pubovaginal sling for destroyed female urethra after long-term urethral catheterization. Urology 43(4): 499-505, 1994.
- 9. Chancellor, MB, Rivas, DA, Abdill, CA, Karasick, S, Ehrlich, SM, Staas, WE: Prospective comparison of external sphincter balloon dilitation and prosthesis placement with external sphincterotomy in spinal cord injured men. Arch Physical Med Rehab 75: 297-305, 1993.
- 10. Chancellor MB, Rivas DA, Liberman SN, Moore J, Staas, WE: Cystoscopic autogenous fat injection for the treatment of vesicoureteral reflux in spinal cord injury. J American Paraplegia Society, 17(4):50-54, 1994.
- 11. Chancellor MB, Rivas DA, Panzer DE, Friedman M, Staas WE: Prospective comparison of topical minoxidil to vacuum constriction device and intracoporal papaverine injection in the treatment of erectile dysfunction due to spinal cord injury. Urology, 43(3): 365-369, 1994.
- 12. Chancellor MB, Rivas DA, Salzman SK: Detrusor-myoplasty to restore micturition. Lancet 343:669, 1994.
- 13. Rivas, DA, Chancellor MB: Complications associated with the use of vacuum constriction devices for erectile dysfunction in the spinal cord injured population. J Am Paraplegia Soc 17:137-140, 1994.

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- 14. Rivas, DA and Chancellor, MB: Prospective comparison of external sphincter prosthesis placement with external sphincterotomy in spinal cord injured men. J Endourol 8:89-93, 1994.
- 15. Rivas, DA and Chancellor, MB: Flexible cystoscopy in spinal cord injury. Paraplegia 32: 454-462, 1994.
- 16. Chancellor MB, Rivas DA, Ackman D, Appell RA, Binard J, Boon TB, Roehrborn CG, Chetner MP, Thorndike WC, Defalco A, Mayo M, Gajewski J, Green B, Bennett J, Foote J, Juma S, Linsenmeyer T, McMillan R, Stone A, Vasquez A: Multicenter trials of UrolumeTM Endourethral Wallstent^R prosthesis for the urinary sphincter in spinal cord injured men. J Urol 152: 924-930, 1994.
- 17. Chancellor MB, Rivas DA, Keeley FX, Lofti MA, Gomella LG: Similarity of the American Urological Association Symptom Index among men with benign prostatic hyperplasia (BPH), urethral obstruction not due to BPH, and detrusor hyperreflexia without outlet obstruction. Brit J Urol, 74: 200-203, 1994.
- 18. Rivas, DA and Chancellor, MB: Utility of the American Urological Association symptom index in the diagnosis and treatment of women with voiding dysfunction. Int Urogyn J 5(4): 202-207, 1994.
- 19. Chancellor, MB, Rivas, DA, and Staas, WE: DDAVP in the urological management of the difficult neurogenic bladder in spinal cord injury: Preliminary report. J Amer Paraplegia Soc 17:165-167, 1994.
- 20. Shenot, P, Rivas, DA, Kalman, DD, Staas WE, Chancellor, MB: Latex allergy manifested in Urological surgery and care of spinal cord injured patients. Arch Phys Med Rehabilitation 75:1263-5, 1994.
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Book Chapters

- 1. Rivas DA, Chancellor MB, Blaivas JG: Interstitial cystitis; current status of diagnosis and management. *In* Mc Guire EJ (Ed): Advances in Urology, Mosby-Year Book, Chicago, IL. vol 7: 229-265, 1994
- 2. Rivas DA, Chancellor MB: Chapter 1. Neuro-urologic anatomy. *In* Chancellor MB and Blaivas JG (Eds.): Genitourinary Complications in Neurologic Disease. Butterworth Heinemann, Stoneham, MA. 3-8, 1995.
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Presentations

- 1. Functional urethral closure with pubovaginal sling for the destroyed female urethra after long-term urethral catheterization. Joint meeting of the American Urogynecology Society and Urodynamic Society, San Antonio, TX, November, 1993.
- 2. Prospective evaluation of external sphincter prosthesis placement with external sphincterotomy in spinal cord injured men. Presented as Essay Contest 1st Prize Winner to the World Congress on Endourology, Florence, Italy, October, 1993.
- 3. Complications associated with the use of vacuum constriction devices for erectile dysfunction in the spinal cord injured population. Annual Convention of the American Paraplegia Society, Las Vegas, NV, September, 1993.
- 4. Autonomic dysreflexia in a rat model of spinal cord injury: effect of pharmacologic agents. Urodynamics Society, American Urological Association Annual Convention, San Antonio, TX, May, 1993.
- 5. Comparison of erectile response to intraurethral, topical, and intracorporal application of vasoactive substances in the rat model of spinal cord injury. American Spinal Injury Association Annual Convention, Philadelphia, PA, April, 1994.
- 6. Comparison of the American Urological Association symptom index between women and men. American Urological Association Annual Convention, San Francisco, California, May, 1994.
- 7. Comparison of erectile response to intraurethral, topical, and intracorporal pharmacotherapy in the rat model of spinal cord injury. American Urological Association Annual Convention, San Francisco, California, May, 1994.
- 8. DDAVP in the symptomatic management of voiding symptoms in men with benign prostatic hyperplasia. American Urological Association Annual Convention, San Francisco, California, May, 1994.
- 9. Endoluminal ultrasound evaluation of urethral diverticula and periurethral mass. American Urological Association Annual Convention, San Francisco, California, May, 1994.

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- 10. Comparison of erectile response to intraurethral, topical, and intracorporal pharmacotherapy in the rat model of spinal cord injury.

 American Paraplegia Society Annual Convention, Las Vegas, NV, September, 1994.
- 11. Long-term follow-up of sphincter stent prosthesis in spinal cord injury.

 American Paraplegia Society Annual Convention, Las Vegas, NV, September, 1994.
- 12. Comparison of erectile response to topical and intraurethral application of minoxidil in the rat model of spinal cord injury to that of the clinical response to topical minoxidil in SCI men. Mid-Atlantic Section of the American Urological Association Annual Meeting, Philadelphia, PA, September 23, 1994.
- 13. A molecular marker for the development of interstitial cystitis in a rat model: isoactin gene expression. NIDDK 1995 Interstitial Cystitis Scientific Research Symposium, National Institutes of Health, Bethesda, MD, January 9, 1995.
- 14. The effect of myomyotomy on bladder rupture in a rat model of bladder augmentation. Urodynamics Society, American Urological Association Annual Convention, Las Vegas, NV, April 23, 1995.
- 15. Contact Nd:YAG laser ablation of the external urinary sphincter in spinal cord injured men with detrusor-sphincter dyssynergia. American Urological Association Annual Convention, Las Vegas, NV, April 25, 1995.
- 16. Isoactin gene expression in the rat model of spinal cord injury; a potential early marker of long-term bladder function and risks. American Urological Association Annual Convention, Las Vegas, NV, April 24, 1995.
- 17. Epidemiology of current treatment for sexual dysfunction in spinal cord injured men in the model spinal cord injury centers. American Spinal Injury Association Annual Convention, Orlando FL, May 1995.
- 18. Bladder smooth muscle gene expression in spinal cord injury; potential early marker of long-term bladder function and risks. American Spinal Injury Association Annual Convention, Orlando FL, May 1995.
- 19. Gracilis muscle dynamic urethral sphincter myoplasty: rat model experience. American Spinal Injury Association Annual Convention, Orlando FL, May 1995.
- 20. A molecular marker for the development of interstitial cystitis in a rat model: Isoactin gene expression. Mid-Atlantic Section of the American Urological Association Annual Meeting, Southampton, Bermuda, September 19, 1995.
- 21. Bladder smooth muscle isoactin gene expression in the rat model of spinal cord injury. American Urological Association Annual Convention, Orlando, FL May 1996.
- 22. Bladder smooth muscle isoactin gene expression in the rat model of spinal cord injury. American Spinal Injury Association Annual Convention, Seattle, WA April 1996.
- 23. Effect of urinary tract reconstruction in neurologically impaired women. American Spinal Injury Association Annual Convention, Seattle, WA April 1996.

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- 24. Gracilis urethromyoplasty- the creation of a new autologous urinary sphincter in neurologically impaired patients. American Spinal Injury Associationn Annual Convention, Seattle, WA April 1996.
- 25. Electrically stimulated skeletal muscle urinary neosphincter for stress urinary incontinence. American Spinal Injury Association Annual Convention, Houston, TX March 1997.
- 26. Intravesical capsaicin for neurogenic bladder dysfunction. American Spinal Injury Association Annual Convention, Houston, TX March 1997.
- 27. Continuous vs. conventional urodynamic studies in spinal cord injured patients.
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- 28. Rivas DA, Chancellor MB, Watanabe T, Shenot PJ, Figueroa TE: Methylprednisolone and mianserin improve recovery of bladder function after spinal cord inury in the rat model. American Spinal Injury Association Annual Convention, Houston, TX March 1997.
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- 31. Rivas DA, Watanabe T, Shenot PJ, Huang B, Figueroa TE, Chancellor MB: Methylprednisolone and mianserin improve recovery of bladder function after spinal cord inury in the rat model. American Urological Association Annual Convention, New Orleans, LA April 1997.
- 32. Rivas DA, Hong R, Watanabe T, Crewalk J, Quinn D, Bourgeois I, Chancellor MB: An autologous skeletal muscle urinary neosphincter (gracilis urethromyoplasty) for the treatment of incontinence in neurologically impaired patients. American Urological Association Annual Convention, New Orleans, LA April 1997.
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- 34. Rivas DA, Shenot PJ, Shupp-Byrne D, McCue P, Sedor J, Chancellor MB, deGroat WC, Fraser MO, Jordan ML. Effects of ethanol and oil vehicles for intravesical capsaicin treatment. American Spinal Injury Association Annual Convention, Cleveland OH March 1998.

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- 35. Rivas DA, Shenot PJ, Figueroa TE, McHugh K, Shupp-Byrne D, Huang B, Chancellor MB. Bladder smooth muscle isoactin gene expression in the rat model of spinal cord injury. American Spinal Injury Association Annual Convention, Cleveland OH March 1998.
- 36. Rivas, D.A., Shenot, P.J., Stuligowa, K., Quinn, D., Green, B., Fraser, M., Kim, D., Lavelle, J., Erickson, J. deGroat, W.C., and Chancellor, M.B.: Intravesical resinaferatoxin (RTX) treatment of detrusor hyperreflexia: Results of a randomized double-blind, placebo-controlled trial. American Urological Association Annual Convention Dallas, TX, May 1999.
- 37. Rivas, D.A., Shenot, P.J., Stuligowa, K., Quinn, D., Green, B., Fraser, M., Kim, D., Lavelle, J., Erickson, J. deGroat, W.C., and Chancellor, M.B.: Intravesical resinaferatoxin (RTX) treatment of detrusor hyperreflexia: Results of a randomized double-blind, placebo-controlled trial. Society for Female Urology and Urodynamics, American Urological Association Annual Convention, Dallas, TX, May 1999.
- 38. Rivas, DA: The vanilloids: capsaicin and resiniferatoxin: novel therapy for the treatment of detrusor hyperreflexia. International Continence Society Annual Convention, Denver, CO Agust 23, 1999.
- 39. Rivas DA, Shenot PJ, Green B, Frazer MO, deGroat WC, Chancellor MB: Intravesical resiniferatoxin (RTX) treatment of detrusor hyperreflexia: results of a randomized, placebo-controlled, multicenter trial. American Paraplegia Society Annual Convention, Las Vegas NV, September 1999
- 40. Rivas, DA, Chancellor, MB, Green, B, Quinn D, Shenot, PJ: Intravesical resinaferatoxin (RTX) treatment of detrusor hyperreflexia: Results of a randomized double-blind, placebo-controlled trial. Mid-Atlantic Section of American Urological Association Annual Convention, Hilton Head, SC, October 1999.
- 41. Rivas DA, Figueroa TE, Hay D, Oh J, Shenot PJ. Evidence for a role of tachykinins in detrusor hyperreflexia: a study of NK3 antagonists in the rat model of spinal cord injury. American Spinal Injury Association Annual Convention, Chicago, IL April 14, 2000.
- 42. Rivas DA, Shenot PJ, Vasavada SP, Quinn D, Hubert C, Chancellor MB, deGroat WC, Kim DY, Erikson J, Green B, Kennelly M. Intravesical resiniferatoxin (RTX) increases bladder capacity and improves continence in patients with refractory detrusor hyperreflexia: a randomized, blinded, placebo-controlled trial. Society for Urodynamics and Female Urology, American Urological Association Annual Convention, Atlanta, GA April 29,2000.
- 43. Rivas DA, Schmidt RA, van Kerrebroeck PEV, Janknegt RA, Lycklama a Nijolt AAB, Hassouna MH, Siegel SW, Jonas U, Fowler CJ. Interstim therapy: proper placement in the treatment ladder. American Urological Association Annual Convention, Atlanta, GA May 2,2000.
- 44. Rivas DA, Shenot PJ, Vasavada SP, Quinn D, Hubert C, Chancellor MB, deGroat WC, Kim DY, Erikson J, Green B, Kennelly M. Intravesical resiniferatoxin (RTX) increases bladder capacity and improves continence in patients with refractory detrusor hyperreflexia: a randomized, blinded, placebo-controlled trial, American Urological Association Annual Convention, Atlanta, GA May 2, 2000.

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- 45. Rivas DA, Figueroa TE, Hay D, Shenot PJ. Evidence for a role of tachykinins in detrusor hyperreflexia: a study of NK3 antagonists in the rat model of spinal cord injury. American Urological Association Annual Convention, Atlanta, GA May 2, 2000.
- 46. Rivas DA, Shenot PJ. Holmium: YAG laser lithotripsy of bladder calculi in spinal cord injured patients. American Paraplegia Society Annual Conference, Las Vegas, NV Septenber 5, 2000.
- 47. Rivas DA, Chancellor MB, Sathyan G, Gupta S. Effect on Salivary output following controlled-release oxybutynin and tolterodine. Mid-Atlantic Section of American Urological Association Annual Convention, Rio Grand, PR October 15, 2001.
- 48. Rivas DA, Gomella LG, Hirsch IH, Strup SE, Shenot PJ, Casale P, Mulholland SG. Transurethral microwave thermotherapy (TUMT) of the prostate without IV sedation: Results of a single US center using both low-energy and high-energy protocols. Mid-Atlantic Section of American Urological Association Annual Convention, Rio Grand, PR October 18, 2001.
- 49. Rivas DA. Urethral suspension surgery as treatment for post-prostatectomy incontinnee: the new millennnium sling. Invited speaker, Mid-Atlantic Section of American Urological Association Annual Convention, Rio Grand, PR October 18, 2001.

Accepted Abstracts

- 1. Erhard, MJ, Chancellor, MB, Rivas, DA, Kiilholma, P: Pubovaginal sling for the treatment of destroyed female urethra secondary to long-term foley catheter drainage. American Spinal Injury Association Annual Convention, May 10-12, 1993, San Diego, CA.
- 2. Chancellor, MB, Rivas, DA, Huang, B, Hirsch, IH, Filmer, RB, Salzman, SK: Micturition patterns after experimental rat model spinal cord injury. American Spinal Injury Association Annual Convention, May 10-12, 1993, San Diego, CA.
- 3. Chancellor, MB, Liberman, S, Rivas, DA, Moore, J: Autogenous fat injection in the treatment of vesicoureteral reflux in spinal cord injury: preliminary report. American Spinal Injury Association Annual Convention, May 10-12, 1993, San Diego, CA.
- 4. Erhard, MJ, Chancellor, MB, Rivas, DA, Staas, WE: Evaluation of terazosin for the treatment of voiding dysfunction in spinal cord injury. American Spinal Injury Association Annual Convention, May 10-12, 1993, San Diego, CA.
- 5. Rivas, DA, Chancellor, MB, Huang, B, Salzman, SK: Autonomic dysreflexia in a rat model spinal cord injury and the effect of pharmacologic agents. Urodynamics Society, American Urological Association Annual Convention, May 15, 1993, San Antonio TX.

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